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JULIE CRUZ and RAY CRUZ

IN THE UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JULIE CRUZ and RAY CRUZ, Plaintiffs, vs. JOHNSON & JOHNSON; ETHICON, INC.; and COLOPLAST CORP., Defendants.	**CASE NO: 8:18-cv-01539-JVS-JDE** **PLAINTIFFS JULIE AND RAY CRUZ'S SECOND AMENDED COMPLAINT AND JURY DEMAND**

Plaintiffs Julie Cruz and Ray Cruz, by and through their attorneys, Hansen, Kohls, Sommer & Jacob, LLP, bring this Complaint and Jury Demand against Defendants and allege the following based upon personal knowledge, information and belief and investigation of counsel.

NATURE OF ACTION

1. This action seeks to recover damages for injuries sustained by Plaintiffs Julie Cruz and Ray Cruz as the direct and proximate result of the wrongful conduct of defendants in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting and selling of transvaginal mesh.

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PARTIES

2. Plaintiffs Julie Cruz and Ray Cruz are and were at all times alleged herein, citizens and residents of California. Plaintiffs have suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

3. Defendant, Johnson & Johnson is a corporation, incorporated in New Jersey and according to its website, the world's largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its pelvic floor repair products. For diversity purposes, Johnson & Johnson is a citizen of New Jersey.

4. Defendant, Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson with its principal place of business located in Somerville, New Jersey. Defendant Ethicon is incorporated in New Jersey. For diversity purposes, Ethicon is a citizen of New Jersey.

5. Defendant Coloplast Corp. ("Coloplast") is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Defendant Coloplast is incorporated in Delaware. For diversity purposes, Coloplast is a citizen of Minnesota and Delaware.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

7. Venue in this action is proper pursuant to 28 U.S.C. § 1391(a) and (c), as a substantial number of the events, actions, and omissions giving rise to Plaintiffs' claim occurred in this district. At all times material hereto, Defendants were for profit corporations authorized to and doing substantial business in the State of California.

8. At all times alleged herein, Ethicon included and includes any and all parents,

subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

9. Defendant Ethicon develops technology to diagnose and treat conditions related to the pelvic health of women.

10. At all times relevant herein, Ethicon was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, packaging, labeling, and selling such devices, including the Gynecare TVT™ Obturator System. Ethicon manufactures, markets, advertises, promotes, and sells the Gynecare TVT™ Obturator System worldwide.

11. At all times relevant herein, Ethicon designed and manufactured the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

12. At all times relevant herein, Ethicon packaged the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

13. At all times relevant herein, Ethicon labeled the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

14. At all times relevant herein, Ethicon sold the Gynecare TVT™ Obturator System products throughout the Unites States, including the State of California.

15. Defendant Coloplast is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411.

16. At all times alleged herein, Coloplast included and includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

17. Defendant Coloplast develops technology to diagnose and treat conditions related to the pelvic health of women.

18. At all times relevant herein, Coloplast was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, packaging, labeling, and selling such devices, including the Restorelle® Y Polypropylene Mesh. Coloplast manufactures, markets, advertises, promotes, and sells the Restorelle® Y Polypropylene Mesh worldwide.

19. At all times relevant herein, Coloplast designed and manufactured the Restorelle® Y Polypropylene Mesh products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

20. At all times relevant herein, Coloplast packaged the Restorelle® Y Polypropylene Mesh products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

21. At all times relevant herein, Coloplast labeled the Restorelle® Y Polypropylene Mesh products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

22. At all times relevant herein, Coloplast sold the Restorelle® Y Polypropylene Mesh products throughout the Unites States, including the State of California.

23. This is an action for damages in excess of $75,000, exclusive of interest, costs and attorneys' fees. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

24. Defendants are registered to transact business in the State of California.

25. Defendants have transacted business within the State of California and this Court has personal jurisdiction over Defendants under the California Long Arm Statute, *Cal. Code Civ. Proc. § 410.10.*

26. Defendants have committed a tortious injury in the State of California caused by their acts and/or omissions outside of this state and they are subject to jurisdiction in this Court under the California Long Arm Statute, *Cal. Code Civ. Proc. § 410.10,* by virtue of their regular conduct and solicitation of business in this state, their continued derivation of substantial revenue

from goods used or consumed in California, and based on their otherwise persistent course of conduct in California.

27. Defendants have purposefully and systematically committed acts and consummated transactions in the State of California from which they have derived and continue to derive substantial revenues, and they have otherwise committed purposeful actions in the State of California which should have led them to reasonably anticipate being hauled into court in California. Jurisdiction is proper in this Court with respect to Defendants.

28. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the Central District of California and venue is proper in the Central District of California under 28 U.S.C. § 1391 (a) and (c).

FACTUAL BACKGROUND

A. As Against Johnson & Johnson and Ethicon

29. Plaintiff Julie Cruz was implanted with a Gynecare TVT™ Obturator System product, Device No. 810081, Lot No. 3734785, during surgery performed by Melanie Santos, M.D. at the St. Jude Medical Center in Fullerton, California on or about February 17, 2014.

30. Defendant Ethicon at all times material hereto, manufactured the Gynecare TVT™ Obturator System products.

31. Defendant Ethicon at all times material hereto, manufactured the Gynecare TVT™ Obturator System products, Device No. 810081, Lot No. 3734785.

32. The Gynecare TVT™ Obturator System product was implanted in Plaintiff Julie Cruz to treat her for stress urinary incontinence and other symptoms, the use for which the product was designed, marketed and sold.

33. Defendant Ethicon at all times material hereto, was engaged in the business of placing medical devices in the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Gynecare TVT™ Obturator System product which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

34. Defendant Ethicon at all times material hereto designed the Gynecare TVT™

Obturator System products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

35. Defendant Ethicon at all times material hereto marketed the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff Julie Cruz, which gives rise to the Plaintiffs' claims asserted herein.

36. Defendant Ethicon at all times material hereto marketed the Gynecare TVT™ Obturator System products through television, print and internet advertising and by sending sales representatives throughout the United States and to the State of California to promote the sale of the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff Julie Cruz.

37. Defendant Ethicon at all times material hereto packaged the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff Julie Cruz.

38. Defendant Ethicon at all times material hereto labeled the Gynecare TVT™ Obturator System products by placing its name on the outside of the Gynecare TVT™ Obturator System's packaging.

39. Defendant Ethicon at all times material hereto, labeled the Gynecare TVT™ Obturator System products by placing its name on the paper inside the Gynecare TVT™ Obturator System product's packaging.

40. Defendant Ethicon at all times material hereto, sold the Gynecare TVT™ Obturator System products throughout the United States, including the State of California.

41. Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act ("Section 510(k)") allows the marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 29, 1976.

42. A predicate device is one that the Food and Drug Administration ("FDA") has placed into one of three classification categories and "cleared" for marketing. These regulatory classification categories include Class I, Class II, and Class III medical devices.

43. Under Section 510(k), a manufacturer must provide a premarket notification that

allows the FDA to determine whether the device is substantially equivalent to a predicate device.

44. Under Section 510(k), no formal review for safety or efficacy is required.

45. The Gynecare TVT™ Obturator System product manufactured by Ethicon is considered a Class II medical device under FDA's medical device regulatory classification system.

46. Prior to 2005 Defendant sought and obtained the FDA's approval to market the Gynecare TVT™ Obturator System product under Section 510(k).

47. Ethicon was, or should have been, aware of the dangers inherent in Gynecare TVT™ Obturator System products generally, notwithstanding the fact that these products were "cleared" for sale by the FDA.

48. As a result of having the Gynecare TVT™ Obturator System product implanted in her, Plaintiff Julie Cruz has experienced significant mental and physical pain, disability, suffering, has sustained permanent injury, and permanent and substantial physical deformity, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income, has endured impaired physical relations during intimacy, and other damages.

B. As Against Coloplast

49. Plaintiff Julie Cruz was implanted with Restorelle® Y Polypropylene Mesh product, Device No. 501520, Lot No. 3698624, during surgery performed by Melanie Santos, M.D. at the St. Jude Medical Center in Fullerton, California on or about February 17, 2014.

50. Defendant Coloplast at all times material hereto, manufactured the Restorelle® Y Polypropylene Mesh product.

51. Defendant Coloplast at all times material hereto, manufactured the Restorelle® Y Polypropylene Mesh, Device No. 501520, Lot No. 3698624.

52. Prior to Plaintiff's surgery, her treating physician, as well as Plaintiff, were exposed to the advertising and marketing campaign directed by Coloplast.

53. Plaintiff and her physician, either through direct promotional contact with Coloplast Sales Representatives, Lab Faculty, through word-of-mouth with other healthcare

providers, and/or through promotional materials, received the information Coloplast intended Plaintiff and her physician to receive and/or view, claiming that the Restorelle® Y Polypropylene Mesh was safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence.

54. Plaintiff returned to her physician due to complications and problems attributed to Coloplast's Restorelle® Y Polypropylene Mesh. An exam showed a piece of exposed mesh visible through her vaginal wall accompanied with a foul smelling discharge.

55. Due to these complications and problems attributed to Coloplast's Restorelle® Y Polypropylene Mesh on or about August 29, 2016, at OC Anaheim Medical Center located in Anaheim, California, Plaintiff's physician excised a portion of the Restorelle® Y Polypropylene Mesh.

56. As a direct and proximate result of the use of the Coloplast Restorelle® Y Polypropylene Mesh, Plaintiff Julie Cruz suffered, and continues to suffer, serious bodily injury and harm, including, but not limited to, the excision of the exposed Coloplast Restorelle® Y Polypropylene Mesh.

57. As a direct and proximate result of the use of the Coloplast Restorelle® Y Polypropylene Mesh, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

58. As a direct and proximate result of the use of the Coloplast Restorelle® Y Polypropylene Mesh, Plaintiff Julie Cruz continues to receive medical treatment and could potentially undergo further surgeries to remove more mesh.

59. Coloplast develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution of the Restorelle® Y Polypropylene Mesh for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

60. At all relevant times, Restorelle® Y Polypropylene Mesh was used to treat pelvic organ prolapse and stress urinary incontinence.

61. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder, bowels,

rectum, small intestine, and uterus, drops, or "prolapses," from its normal position and pushes against the wall of the vagina. Prolapses can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time.

62. Stress urinary incontinence is a type of incontinence caused by leakage of urine during moments of physical stress. It affects 20-40% of all women.

63. Surgical mesh, including transvaginal mesh, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material and absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most transvaginal meshes are comprised of non-absorbable synthetic polypropylene. Upon information and belief, the Restorelle® Y Polypropylene Mesh is comprised of a synthetic, petroleum-based mesh.

64. Coloplast's Restorelle® Y Polypropylene Mesh contains monofilament polypropylene mesh and/or collagen and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Coloplast's Restorelle® Y Polypropylene Mesh. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Coloplast's collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Coloplast's collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal tissue. Animal collagen is harsh upon the female pelvic tissue. It hardens in the body. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

C. Facts Common to All Defendants

65. In 1996, the FDA cleared the first mesh products for use in the treatment of stress urinary incontinence (SUI). These mesh products include transvaginal mesh, including the Restorelle® Y Polypropylene Mesh, which was manufactured, marketed and distributed by Coloplast. These products are approved by the FDA under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to Restorelle® Y Polypropylene Mesh.

66. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare".

67. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain."

68. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

69. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

70. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by

patients who undergo traditional surgery without mesh."

71. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original.)

72. The FDA White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non- mesh repair."

73. In its White Paper, the FDA advised doctors to, inter alia, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

74. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

75. Defendants knew or should have known about the risks and complications identified in the FDA Safety Communication.

76. Defendants knew or should have known that their products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

77. The scientific evidence shows that the material from which Defendants' products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the products, including Plaintiff Julie Cruz.

78. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff Julie Cruz.

79. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as

an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." Defendants' products were unreasonably susceptible to degradation and fragmentation inside the body.

80. Defendants' products were unreasonably susceptible to shrinkage and contraction inside the body.

81. Defendants' products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subjected to prolonged tension inside the body.

82. Defendants' products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

83. Defendants omitted the risks, dangers, defects, and disadvantages of their products, and advertised, promoted, marketed, sold and distributed the products as safe medical devices when Defendants knew or should have known that the products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in some patients, including Plaintiff Julie Cruz, catastrophic injuries.

84. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendants' products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Julie Cruz, making them defective under the law.

85. The specific nature of the products' defects includes, but is not limited to, the following:

a. the use of polypropylene and collagen material in the products and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the products to be inserted into and through an area of the body with

high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the products, including, but not limited to, the propensity of the products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. the propensity of the products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the

manufacturers' instructions.

86. Defendants' products are also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

m. the products' propensities to contract, retract, and/or shrink inside the body;

n. the products' propensities for degradation, fragmentation and/or creep;

o. the products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

p. the rate and manner of mesh erosion or extrusion;

q. the risk of chronic inflammation resulting from the products;

r. the risk of chronic infections resulting from the products;

s. the risk of permanent vaginal or pelvic scarring as a result of the products;

t. the risk of recurrent, intractable pelvic pain and other pain resulting from the products;

u. the need for corrective or revision surgery to adjust or remove the products;

v. the severity of complications that could arise as a result of implantation of the products;

w. the hazards associated with the products;

x. the products' defects described herein;

y. treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible available alternatives;

z. treatment of pelvic organ prolapse and stress urinary incontinence with the products exposes patients to greater risk than feasible available alternatives;

aa. treatment of pelvic organ prolapse and stress urinary incontinence with the products makes future surgical repair more difficult than feasible available alternatives;

bb. use of the products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

cc. removal of the products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

dd. complete removal of the products may not be possible and may not result in complete resolution of the complications, including pain.

87. Defendants have underreported information about the propensity of the products to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the products through various means and media.

88. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the products.

89. Defendants failed to design and establish a safe, effective procedure for removal of the products, or to determine if a safe, effective procedure for removal of the products exists.

90. Feasible and suitable alternatives to the products have existed at all times relevant that do not present the same frequency or severity of risks as do the products.

91. The products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

92. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the products and the aftercare of patients implanted with the Products.

93. The product or products implanted in Plaintiff Julie Cruz were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

94. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

95. In many cases, including Plaintiff Julie Cruz, women have been forced to undergo

extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

96. The medical and scientific literature studying the effects of Defendants' mesh products, like that of the products implanted in the relevant Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the products.

97. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

98. At all relevant times herein, Defendants continued to promote the products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

99. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the products.

100. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff Julie Cruz and the general public on notice of the dangers and adverse effects caused by implantation of the products.

101. The products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in light of Defendants' knowledge of lack of safety.

102. As a result of having the products implanted in her, Plaintiff Julie Cruz has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

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CAUSES OF ACTION

COUNT I: NEGLIGENCE

103. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

104. Defendant Ethicon had a duty to individuals, including Plaintiffs, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Gynecare TVT™ Obturator System.

105. Defendant Ethicon was negligent in failing to use reasonable care in designing, manufacturing, labeling, packaging, and selling the Gynecare TVT™ Obturator System.

106. Defendant Coloplast had a duty to individuals, including Plaintiffs, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Restorelle® Y Polypropylene Mesh.

107. Defendant Coloplast was negligent in failing to use reasonable care in designing, manufacturing, labeling, packaging, and selling the Restorelle® Y Polypropylene Mesh.

108. As a direct and proximate result of Defendants' negligence, Plaintiff Julie Cruz was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY: MANUFACTURING DEFECT

109. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

110. The Gynecare TVT™ Obturator System product implanted in Plaintiff Julie Cruz was not reasonably safe for its intended use and was defective as a matter of law with respect to its manufacture.

111. The Restorelle® Y Polypropylene Mesh product implanted in Plaintiff Julie Cruz was not reasonably safe for its intended use and was defective as a matter of law with respect to its manufacture.

112. As a direct and proximate result of the products' aforementioned defects, Plaintiff

Julie Cruz was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

113. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT III: STRICT LIABILITY: FAILURE TO WARN

114. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

115. The Gynecare TVT™ Obturator System implanted in Plaintiff Julie Cruz was not reasonably safe for its intended uses and was defective as a matter of law due to its lack of appropriate and necessary warnings.

116. The Restorelle® Y Polypropylene Mesh implanted in Plaintiff Julie Cruz was not reasonably safe for its intended uses and was defective as a matter of law due to its lack of appropriate and necessary warnings.

117. As a direct and proximate result of the products' aforementioned defects as described herein, Plaintiff Julie Cruz was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, or other damages.

118. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling and selling a defective product.

COUNT IV: FRAUDULENT CONCEALMENT

119. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

120. At all times during the course of dealings between Defendants and Plaintiffs, and/or her healthcare providers, and/or the FDA, Ethicon and Johnson & Johnson misrepresented the safety of the Gynecare TVT™ Obturator System for its intended use.

121. At all times during the course of dealings between Defendants and Plaintiffs,

and/or her healthcare providers, and/or the FDA, Coloplast misrepresented the safety of the Restorelle® Y Polypropylene Mesh for its intended use.

122. Defendants knew or were reckless in not knowing that their representations were false.

123. Ethicon and Johnson & Johnson were under a duty to disclose to Plaintiff Julie Cruz, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Gynecare TVT™ Obturator System including, but not limited to, the risk that the mesh can contract causing the vagina to contract and eventually perforate the vaginal wall.

124. Ethicon and Johnson & Johnson had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to the Plaintiff who was implanted with the Gynecare TVT™ Obturator System.

125. Ethicon and Johnson & Johnson's concealment and omissions of material facts concerning, inter alia, the safety of the Gynecare TVT™ Obturator System were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, her physicians, hospitals and healthcare providers into reliance and use of the Gynecare TVT™ Obturator System, and to cause them to purchase and/or use the Gynecare TVT™ Obturator System.

126. Ethicon and Johnson & Johnson knew that Plaintiff Julie Cruz and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of fact surrounding the Gynecare TVT™ Obturator System, as set forth herein.

127. Coloplast was under a duty to disclose to Plaintiff Julie Cruz and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Restorelle® Y Polypropylene Mesh including, but not limited to, the risk that the mesh can contract causing the vagina to contract and eventually perforate the vaginal wall.

128. Coloplast had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to the Plaintiff who was implanted with the Restorelle® Y Polypropylene Mesh.

129. Coloplast's concealment and omissions of material facts concerning, inter alia, the safety of the Restorelle® Y Polypropylene Mesh were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, her physicians, hospitals and healthcare providers into reliance and use of the Restorelle® Y Polypropylene Mesh, and to cause them to purchase and/or use the Restorelle® Y Polypropylene Mesh.

130. Coloplast knew that Plaintiff Julie Cruz and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of fact surrounding the Restorelle® Y Contour Polypropylene Mesh, as set forth herein.

131. Coloplast used three of Mpathy Medical Ltd.'s devices as predicate devices to develop and manufacture the Restorelle polypropylene mesh and to submit for approval of the 510(k) premarket notification ("510(k)") to the FDA. The first predicate device was Minimesh polypropylene mesh, 510 (k) No. K041632, manufactured by Mpathy Medical Ltd., which was submitted to the FDA for approval on or around June 2004 and approved by the 510(k) process on or around November 2004. Approximately two (2) years later on or around January 2006, Mpathy Medical Ltd, manufactured an updated Minimesh polypropylene mesh, 510(k) No. K053361, and submitted that mesh to the FDA for approval for the 510(k) process, which was approved on or around February 2006. On or around July 2009, Mpathy Medical manufactured a third predicate device polypropylene mesh, named Restorelle polypropylene mesh, 510(k) No. 092207, and submitted this new and updated mesh to the FDA for approval on or around July 2009, which approval was granted on or around August 2009.

132. Coloplast used the above-named predicate meshes, 510(k) No's. K041632, K053361 and K092207, to manufacture and develop the Restorelle polypropylene mesh. On or around December 2010, Coloplast manufactured the Restorelle polypropylene mesh, 510(k) No. K103568, and submitted a 510(k) proposal on or around December 2010 to the FDA for approval, which was granted on or around December 2010. Approximately 2 years later in May 2012, Coloplast manufactured the Restorelle Y, 510(k) No. K112322, using the Restorelle Y mesh from Mpathy polypropylene mesh, 510(k) No. K092207, and Bard's Alyte Y-Mesh Graft, 510(k) No.

K101722, as predicate devices, and submitted a 510(k) proposal to the FDA for approval on or around May 2012 which was granted on or around May 2012.

133. Coloplast continued to manufacture and update its Restorelle mesh. On or around November 2012, Coloplast manufactured the Restorelle® Y Contour, 510(k) No. K123914, using the Restorelle Y, 510(k) No. K112322, as a predicate device and submitted it to the FDA for approval on or around December 2012 and it was approved on or around March 2013. Approximately one year later, Coloplast developed and manufactured the Restorelle® Y Contour Polypropylene Mesh, 510(k) No. K140116, using the Restorelle® Y, 510(k) No. K112322, as a predicate device, and submitted it to the FDA for approval on or around February 10, 2014 and it was approved on or around February 14, 2014.

134. Coloplast's Restorelle® Y Contour Polypropylene Mesh, Lot No. 3698624, Item No. 501520, was marketed and sold by Coloplast's Territorial Manager, Ken Rodman, and according to Coloplast's territorial manager's job description, the territorial manager was "responsible for achieving territory sales objectives through selling activities which include cultivating business partnerships with key decision makers, product-in-services, driving marketing share and sales growth. You will target key customers by selling and servicing Coloplast's portfolio of Continence Care products". According to Ken Rodman's Linked In profile, he has been the territorial manager for Coloplast from 2001 till the present day for the greater Los Angeles area. The sale of the Restorelle® Y Contour Polypropylene Mesh, was represented, marketed and sold by Ken Rodman at all times relevant herein.

135. The Restorelle® Y Contour Polypropylene Mesh was submitted by Coloplast on or about February 10, 2014 and was approved by the FDA on or around February 12, 2014. Plaintiff Julie Cruz was implanted with the Restorelle® Y Contour Polypropylene Mesh on February 17, 2014, approximately six days after the FDA 510(k) approval of the Restorelle® Y Contour Polypropylene Mesh. Coloplast continued to manufacture and design several variations of the Restorelle polypropylene mesh, including several variations of the Restorelle polypropylene mesh, from 2010-2014, and failed to adequately test it on human subjects or complete whole 12 month follow up studies. Coloplast used the 510(k) process to fast track the

device, and marketed the Restorelle® Y Contour polypropylene mesh, as a safe and effective product to treat uterovaginal prolapse.

136. The FDA issued two vaguely written warnings regarding the potential dangers of the polypropylene mesh in 2008 and again in 2011. The 2008 FDA warning stated that complications can occur when surgical mesh is used to treat Pelvic Organ Prolapse, including erosion through the vagina, infection, pain, urinary problems and recurrence of the prolapse and/or incontinence. The follow up FDA warning in 2011 identified concerns about the use of surgical mesh for transvaginal repair or pelvic organ prolapse.

137. In 2014, Coloplast's representative, Ken Rodman, promoted and sold the Restorelle® Y Contour polypropylene mesh to Plaintiff's physician, Melanie Santos, MD, in California stating its safety and effectiveness for pelvic organ prolapse. Plaintiff's physician relied on Coloplast's marketing pamphlets and Coloplast's Territorial Manger, Ken Rodman's negligent and misleading statements about the Restorelle® Y Contour Polypropylene Mesh and misleading marketing materials about the product that claimed and stated "a 93.5% clinical cure rate, 99% cure rate transvaginally, less than 1% erosion" as well as omitting material facts about its safety, leading Melanie Santos, MD to implant the Restorelle® Y Contour polypropylene mesh, Device No. 501520, Lot No. 3698624, into Plaintiff Julie Cruz, on or about February 17, 2014 at the St. Jude Medical Center in Fullerton, California.

138. Coloplast committed fraud in that it developed and manufactured the Restorelle® Y Contour polypropylene mesh and failed to adequately inform Plaintiff's doctor of the life altering problems associated with the mesh. Ken Rodman is a territorial manager for Coloplast and Melanie Santos, MD is Plaintiff, Julie Cruz's medical doctor. The transaction of Ken Rodman and Melanie Santos, MD, of the Restorelle® Y Contour polypropylene mesh, for Plaintiff Julie Cruz, established a transactional relationship between Coloplast and Plaintiff's physician Melanie Santos, MD because Dr. Santos was acting as Plaintiff, Julie Cruz's agent and Ken Rodman was acting as Coloplast's agent, thereby establishing a transactional relationship.

139. Coloplast's representative Ken Rodman made false and negligent claims, on or around February 2014, to Melanie Santos, MD, who was located in Orange County, stating that

the Restorelle® Y Contour polypropylene mesh renews and restores a woman's body, as well as improves her quality of life, has the necessary strength, flexibility, durability and surgical adaptability properties which permit the correct adaptation to the various stresses encountered in the body, as stated in the Coloplast brochure.

140. Coloplast had a duty when entering into a transactional relationship to disclose all material facts related to the Restorelle® Y Contour polypropylene mesh to the Plaintiff when selling a consumer product. Absent those disclosures to Plaintiff, Coloplast was intentionally concealing the adverse effects of the Restorelle® Y and the Plaintiff could not have been aware of these omissions because Plaintiff is not and was not privy to Coloplast's proprietary information and therefore could have no access to the necessary information. If Plaintiff had known the potential life altering side effects of the Restorelle® Y, Plaintiff never would have consented to having the Restorelle® Y implanted inside her body. As a result of Coloplast's omissions and misrepresentations Plaintiff Julie Cruz suffered irreparable injuries and will be in constant pain for the rest of her life.

141. Plaintiff Julie Cruz and her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently, and/or purposefully did not include facts that were concerns of and/or omitted by Defendants.

142. As a result of the foregoing acts and omissions, Plaintiff Julie Cruz has suffered severe physical pain and mental anguish.

143. As a result of the foregoing acts and omissions, Plaintiff Julie Cruz required health care and services and incurred medical, health, incidental and related expenses.

COUNT V: CONSTRUCTIVE FRAUD

144. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

145. Ethicon and Johnson & Johnson are in a unique position of knowledge concerning the quality, safety and efficacy of the Gynecare TVT™ Obturator System, which knowledge is not possessed by Plaintiffs or her physicians, and Defendants thereby hold a position of superiority over Plaintiffs and her physicians.

146. Despite their unique and superior knowledge regarding the defective nature of the Gynecare TVT™ Obturator System, Ethicon and Johnson & Johnson continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Gynecare TVT™ Obturator System, as compared to other products and forms of treatment.

147. For example, scientists in a study published in *Obstetrics & Gynecology*, August 2010, found that the complication rate was so high that the clinical trial was halted early.

148. Ethicon and Johnson & Johnson have concealed and suppressed material information, including limiting clinical testing, that would reveal that the Gynecare TVT™ Obturator System had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the products.

149. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the Defendants' Gynecare TVT™ Obturator System. Plaintiffs and the medical community have relied upon Defendants' representations.

150. Coloplast is in a unique position of knowledge concerning the quality, safety and efficacy of the Restorelle® Y Polypropylene Mesh, which knowledge is not possessed by Plaintiffs or her physicians, and Coloplast thereby holds a position of superiority over Plaintiff and her physicians.

151. Coloplast owed and had a fiduciary responsibility to Plaintiff Julie Cruz and Plaintiff's physician to disclose the potential life altering problems arising from the implantation of the Restorelle® Y Contour Polypropylene Mesh and Ken Rodman was acting as an agent for Coloplast and Melanie Santos, MD was acting as an agent for Plaintiff, Julie Cruz. The relationship between the two agents represents a transactional relationship and the omission of material facts by Ken Rodman to Melanie Santos, MD constitutes constructive fraud.

152. Coloplast and Coloplast's territorial manger, Ken Rodman, who was a territory manager for Coloplast for the Central California region and the Greater Los Angeles Area, which

includes Fullerton and Orange County, had extensive knowledge about the defective nature of the Restorelle® Y and failed to disclose accurately and fully the adverse effects of the device to Plaintiff Julie Cruz's physician Melanie Santos. Dr. Melanie Santos relied on Coloplast's representative, Ken Rodman, who was acting on implied authority of Coloplast, to accurately report disparaging information about the device. Without the assurances of Mr. Rodman regarding the safety of the device, neither Plaintiff Julie Cruz nor Plaintiff's physician would have chosen the Restorelle® Y to be implanted inside her body.

153. Furthermore, Ken Rodman, according to Coloplast's territory manager's job description was responsible for "achieving territory sales objectives through selling activities which include cultivating business partnerships with key decision makers, product in-services, driving market share and sales growth. You will target key customers by selling and servicing Coloplast's portfolio of Continence Care products" and Mr. Rodman accordingly targeted and sold the mesh to Melanie Santos, MD, for the purpose of it being permanently implanted inside of Plaintiff, Julie Cruz's body.

154. Plaintiff, Julie Cruz, relied upon statements and representations made to her physician Dr. Melanie Santos, by Ken Rodman in or around February 2014. Ken Rodman intentionally deceived Plaintiff Julie Cruz and her physician Melanie Santos, MD, and that intentional deception by Ken Rodman led Plaintiffs and Plaintiff's physician to reasonably rely upon Ken Rodman's statements, and that reliance on the fraudulent statements led Plaintiff and Plaintiff's physician to purchase and implant the Restorelle® Y in the Plaintiff.

155. Ken Rodman had a fiduciary duty to honestly represent the Restorelle® Y to Plaintiff's medical doctor, Melanie Santos, MD, and his misrepresentations of the Restorelle® Y constituted constructive fraud. The constructive fraud was committed when Mr. Rodman made false misrepresentations to Plaintiff's physician, Melanie Santos, who was an agent for Plaintiff, Julie Cruz, about the safety and efficacy of the Restorelle® Y, for the purpose of inducing Dr. Santos, to purchase the mesh and she justifiably relied on those misrepresentations to help her and Plaintiff, who decided to have the mesh implanted in her, which resulted in continuous and serious lifelong injuries to Plaintiff, Julie Cruz.

156. Despite its unique and superior knowledge regarding the defective nature of the Restorelle® Y Polypropylene Mesh, Coloplast continues to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Restorelle® Y Polypropylene Mesh, as compared to other products and forms of treatment. For example, scientists in a study published in *Obstetrics & Gynecology*, August 2010, found that the complication rate was so high that the clinical trial was halted early.

157. Coloplast has concealed and suppressed material information, including limiting clinical testing, that would reveal that the Defendant's Restorelle® Y Polypropylene Mesh had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Coloplast has misrepresented the safety and efficacy of the products.

158. Upon information and belief, Defendant's misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the Defendants' Restorelle® Y Polypropylene Mesh. Plaintiffs and the medical community have relied upon Defendants' representations.

VI: BREACH OF IMPLIED WARRANTY

159. Plaintiffs incorporate by reference each and every paragraph of the Complaint as if fully set forth herein.

160. Ethicon and Johnson & Johnson impliedly warranted that the Gynecare TVT™ Obturator System was merchantable and fit for the ordinary purposes for which they were intended.

161. When the Gynecare TVT™ Obturator System was implanted in the Plaintiff to treat her pelvic organ prolapse and/or stress urinary incontinence, the products were being used for the ordinary purposes for which they were intended.

162. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Gynecare TVT™ Obturator System implanted in her.

163. Defendants breached these implied warranties of merchantability because the Gynecare TVT™ Obturator System that was implanted in the Plaintiff was neither merchantable nor suited for the intended uses as warranted.

164. Defendants' breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

165. Coloplast impliedly warranted that the Restorelle® Y Polypropylene Mesh was merchantable and was fit for the ordinary purposes for which it was intended.

166. When the Restorelle® Y Polypropylene Mesh was implanted in the Plaintiff to treat her pelvic organ prolapse and/or stress urinary incontinence, the products were being used for the ordinary purposes for which they were intended.

167. The Plaintiff, individually and/or by and through her physician, relied upon Coloplast's implied warranties of merchantability in consenting to have the Restorelle® Y Polypropylene Mesh implanted in her.

168. Coloplast breached these implied warranties of merchantability because the Restorelle® Y Polypropylene Mesh that was implanted in the Plaintiff was neither merchantable nor suited for the intended uses as warranted.

169. Coloplast's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

170. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

171. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their medical providers and engaged in constructive fraud

in their relationship with Plaintiffs and their medical providers. Plaintiffs reasonably relied on Defendants' representations.

172. As a proximate result of the Defendants' conduct, Plaintiff Julie Cruz has been injured, and has sustained and will continue to sustain severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages and possible death.

COUNT VII: NEGLIGENT MISREPRESENTATION

173. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

174. Ethicon and Johnson & Johnson represented that the Gynecare TVT™ Obturator System was a safe and effective method to treat Stress Urinary Incontinence.

175. Ethicon and Johnson & Johnson made these misrepresentations and actively concealed adverse information at a time when Ethicon and Johnson & Johnson knew, or should have known, that the Gynecare TVT™ Obturator System had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, her physicians and the health care industry, generally.

176. Ethicon and Johnson & Johnson negligently and/or intentionally misrepresented or omitted necessary and required information in the product labeling, promotions, and advertisements and instead labeled, promoted and advertised the product as safe and effective and understated the risks associated with the Gynecare TVT™ Obturator System.

177. The aforementioned misrepresentations were untrue and misleading.

178. Ethicon and Johnson & Johnson knew or should have known that these representations were false and made the representations with the intent that Plaintiff Julie Cruz and/or her treating physicians would rely on them, leading to the use of the Gynecare TVT™ Obturator System.

179. Coloplast represented that the Restorelle® Y Polypropylene Mesh was a safe and effective method to treat Stress Urinary Incontinence, and Coloplast's territorial manager, Ken Rodman, omitted and negligently misrepresented that the adverse side effects of the Restorelle®

Y could cause life-long problems such as: chronic vaginal pain, chronic abdominal pain, chronic upper leg and hip pain, dyspareunia and a continual recurrence of incontinence and the need for repeat surgeries that may not fix the problem, and in fact, would exacerbate the Plaintiff's problems.

180. Plaintiffs and Plaintiff's doctor relied on Defendant's statements, which was a substantial factor in deciding to implant the device in Plaintiff, Julie Cruz and Plaintiff was harmed by Ken Rodman's misrepresentation about the safety and effectiveness of the Restorelle® Y. Ken Rodman represented his statements as truth and intended that Dr. Santos rely on those misrepresentations which were a substantial factor in causing Plaintiff, Julie Cruz's injuries. Ken Rodman is responsible for a representation that was not made directly to Plaintiff, Julie Cruz, because he made the representation to Melanie Santos, MD reasonably expecting that it would be repeated to Plaintiff, Julie Cruz. The misrepresentation substantially influenced Dr. Santos to recommend the Restorelle Y to Plaintiff, Julie Cruz who would not have purchased the Restorelle Y, without the misrepresentation.

181. Coloplast and Ken Rodman continued to promote and sell the Restorelle Y in 2014 well after the safety warnings from the FDA in 2008 and 2011, regarding surgical mesh for pelvic organ prolapse. Coloplast and Ken Rodman continually marketed the Restorelle® Y as a safe and effective device for the treatment of pelvic organ prolapse and/or stress urinary incontinence, although they knew or should have known that the Restorelle® Y was in fact not a safe and effective device for treatment of pelvic organ prolapse and/or stress urinary incontinence. In fact, Coloplast had already been sued by other women who had been implanted with the Restorelle® Y and had adverse events associated with the Restorelle® Y that were reported to the FDA.

182. Coloplast's misrepresentations of material facts that pertain to the side effects of the Restorelle® Y induced the Plaintiff and Plaintiff's physician to implant the Restorelle® Y in Plaintiff Julie Cruz. Plaintiffs' reliance on statements made by Coloplast's representatives and Coloplast itself, by omitting these complications on the Instructions for Use, resulted in Plaintiff Julie Cruz being implanted with the defective Restorelle® Y. Ken Rodman and Coloplast were under a duty to truthfully and accurately report any and all adverse effects of the Restorelle® Y to

Melanie Santos, MD simply for the fact that she never would have recommended or purchased the Restorelle® Y to be implanted in Plaintiff, Julie Cruz if not for Ms. Cruz's symptoms and request for surgery, therefore Dr. Santos was acting as an agent for Plaintiff.

183. Coloplast made these misrepresentations and actively concealed adverse information at a time when Coloplast knew, or should have known, that the Restorelle® Y Polypropylene Mesh had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, her physicians and the health care industry, generally.

184. Coloplast negligently and/or intentionally misrepresented or omitted necessary and required information in the product labeling, promotions, and advertisements and instead labeled, promoted and advertised the product as safe and effective and understated the risks associated with the Restorelle® Y Polypropylene Mesh.

185. The aforementioned misrepresentations were untrue and misleading.

186. Coloplast knew or should have known that these representations were false and made the representations with the intent that Plaintiff Julie Cruz and/or her treating physicians would rely on them, leading to the use of the Restorelle® Y Polypropylene Mesh.

187. At the time of Defendants' fraudulent misrepresentations, Plaintiff Julie Cruz and/or her treating physicians were unaware of the falsity of the statements being made and believed them to be true. Plaintiff Julie Cruz and/or her treating physicians justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which Defendants did suppress, conceal, or fail to disclose to Plaintiffs' detriment.

COUNT VIII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

188. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

189. Ethicon and Johnson & Johnson carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Gynecare TVT™ Obturator System to Plaintiffs, carelessly and negligently concealed the harmful effects of the Gynecare TVT™ Obturator System from Plaintiffs, and carelessly and negligently misrepresented the quality,

safety and efficacy of the Gynecare TVT™ Obturator System.

190. Plaintiff Julie Cruz was directly impacted by Ethicon and Johnson & Johnson's carelessness and negligence, in that Plaintiff sustained and will continue to sustain emotional distress, severe physical injuries and/or possible death, economic losses, and other damages as a direct result of being implanted with the Gynecare TVT™ Obturator System sold and distributed by Ethicon and Johnson & Johnson and/or because of the nature of their relationship to the individual implanted with the Gynecare TVT™ Obturator System.

191. Coloplast carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Restorelle® Y Polypropylene Mesh to Plaintiffs, carelessly and negligently concealed the harmful effects of the Restorelle® Y Polypropylene Mesh from Plaintiff Julie Cruz and carelessly and negligently misrepresented the quality, safety and efficacy of the Restorelle® Y Polypropylene Mesh.

192. Plaintiff Julie Cruz was directly impacted by Coloplast's carelessness and negligence, in that Plaintiff sustained and will continue to sustain emotional distress, severe physical injuries and/or possible death, economic losses, and other damages as a direct result of being implanted with the Restorelle® Y Polypropylene Mesh sold and distributed by Coloplast and/or because of the nature of their relationship to the individual implanted with the Restorelle® Y Polypropylene Mesh.

193. As a direct and proximate result of the Defendants' conduct, Plaintiff Julie Cruz has been injured, and has sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, and economic damages.

COUNT IX: BREACH OF EXPRESS WARRANTY

194. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

195. Ethicon and Johnson & Johnson made assurances to the general public, hospitals and health care professionals that the Gynecare TVT™ Obturator System was safe and reasonably fit for its intended purpose. Coloplast made assurances to the general public, hospitals and health care professionals that the Restorelle® Y Polypropylene Mesh was safe and

reasonably fit for its intended purpose.

196. Plaintiff Julie Cruz and/or her health care provider chose the Gynecare TVT™ Obturator System and the Restorelle® Y Polypropylene Mesh based upon Defendants' respective warranties and representations regarding the safety and fitness of the Gynecare TVT™ Obturator System and the Restorelle® Y Polypropylene Mesh.

197. Plaintiff Julie Cruz, individually and/or by and through her physician, reasonably relied upon Defendants' respective express warranties and guarantees that the Gynecare TVT™ Obturator System and the Restorelle® Y Polypropylene Mesh were safe, merchantable and reasonably fit for their intended purposes.

198. Defendants breached these express warranties because the Gynecare TVT™ Obturator System and the Restorelle® Y Polypropylene Mesh implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants represented.

199. Ethicon/Johnson & Johnson made assurances to the general public, hospitals and health care professionals that the Gynecare TVT™ Obturator System Mesh was safe and reasonably fit for its intended purpose. Coloplast made assurances to the general public, hospitals and health care professionals that the Restorelle® Y Polypropylene Mesh was safe and reasonably fit for its intended purpose.

200. Plaintiff Julie Cruz and/or her health care provider chose the Gynecare TVT™ Obturator System Mesh based upon Defendants' warranties and representations regarding the safety and fitness of the Gynecare TVT™ Obturator System Mesh.

201. Plaintiff Julie Cruz and/or her health care provider chose the Restorelle® Y Polypropylene Mesh based upon Defendants' warranties and representations regarding the safety and fitness of the Restorelle® Y Polypropylene Mesh.

202. Plaintiff Julie Cruz, individually and/or by and through her physician, reasonably relied upon Defendants' respective express warranties and guarantees that the Gynecare TVT™ Obturator System Mesh and the Restorelle® Y Polypropylene Mesh was safe, merchantable and reasonably fit for their intended purposes.

203. Defendants breached these express warranties because the Gynecare TVT™

Obturator System Mesh and the Restorelle® Y Polypropylene Mesh implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants represented.

204. Defendants' breaches of express warranties resulted in the implantation of an unreasonably dangerous and defective products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

205. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff Julie Cruz was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT X: GROSS NEGLIGENCE

206. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

207. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and for which Plaintiffs will seek at the appropriate time under governing law, the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with the applicable federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants knowing that it was false or with reckless disregard as to its truth and as a perspective assertion, with the intent that the representation would be acted on by Plaintiffs.

208. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

209. Plaintiffs therefore will seek to assert claims for exemplary damages at the

appropriate time under governing law in an amount within the jurisdictional limits of the Court.

210. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XI: UNJUST ENRICHMENT

211. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

212. Plaintiffs paid for the Gynecare TVT™ Obturator System for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar conditions.

213. Ethicon and Johnson & Johnson have accepted payment by Plaintiffs and others on Plaintiffs' behalf for the purchase of the Gynecare TVT™ Obturator System.

214. Plaintiffs paid for the Restorelle® Y Polypropylene Mesh for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar conditions.

215. Coloplast has accepted payment by Plaintiffs and others on Plaintiffs' behalf for the purchase of the Restorelle® Y Polypropylene Mesh.

216. Plaintiffs have not received the safe and effective medical devices for which they paid.

217. It would be inequitable for Defendants to keep this money since Plaintiffs did not in fact receive a safe and effective medical device as represented by Defendants.

COUNT XII: LOSS OF CONSORTIUM

218. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

219. As a direct and proximate result of the above-described injuries sustained by Plaintiff Julie Cruz, where applicable, her husband, Ray Cruz, has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

COUNT XIII: PUNITIVE DAMAGES

220. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

221. Ethicon and Johnson & Johnson knew or should have known that the Gynecare TVT™ Obturator System was defective and presented unreasonable risks of harm to Plaintiff Julie Cruz.

222. Ethicon and Johnson & Johnson sold the Gynecare TVT™ Obturator System to Plaintiff's health care providers and other providers in California and throughout the United States without doing adequate testing to ensure that the Gynecare TVT™ Obturator System was reasonably safe for implantation in the female pelvic area.

223. Ethicon and Johnson & Johnson sold the Gynecare TVT™ Obturator System to Plaintiff's health care providers and other health care providers in California and throughout the United States without doing adequate testing to determine whether the Gynecare TVT™ Obturator System degraded *in vivo*. The Gynecare TVT™ Obturator System does, in fact, degrade *in vivo*, which causes the severe and debilitating injuries suffered by Plaintiff Julie Cruz and numerous other women.

224. Ethicon and Johnson & Johnson ignored reports from health care providers throughout the United States of the Gynecare TVT™ Obturator System's failures to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff Julie Cruz and numerous other women. Rather than doing adequate testing to rule out the Gynecare TVT™ Obturator System's design flaws or the processes by which the Gynecare TVT™ Obturator System is manufactured as the cause of these severe and debilitating injuries, Ethicon and Johnson & Johnson chose instead to instruct its sales forces to downplay the Gynecare TVT™ Obturator System's risks, and continued to market and sell the Gynecare TVT™ Obturator System as safe and effective treatments of Stress Urinary Incontinence.

225. Coloplast knew or should have known that the Restorelle® Y Polypropylene Mesh was defective and presented unreasonable risks of harm to Plaintiff Julie Cruz.

226. Coloplast sold the Restorelle® Y Polypropylene Mesh to Plaintiff's health care providers and other providers in California and throughout the United States without doing

adequate testing to ensure that the Restorelle® Y Polypropylene Mesh was reasonably safe for implantation in the female pelvic area.

227. Coloplast sold the Restorelle® Y Polypropylene Mesh to Plaintiff's health care providers and other health care providers in California and throughout the United States without doing adequate testing to determine whether the Restorelle® Y Polypropylene Mesh degraded *in vivo*. The Restorelle® Y Polypropylene Mesh does, in fact, degrade *in vivo*, which causes the severe and debilitating injuries suffered by Plaintiffs and numerous other women.

228. Coloplast ignored reports from health care providers throughout the United States of the Restorelle® Y Polypropylene Mesh's failures to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff Julie Cruz and numerous other women. Rather than doing adequate testing to rule out the Restorelle® Y Polypropylene Mesh's design flaws or the processes by which the Restorelle® Y Polypropylene Mesh is manufactured as the cause of these severe and debilitating injuries, Coloplast chose instead to instruct its sales forces to downplay the Restorelle® Y Polypropylene Mesh risks, and continued to market and sell the Restorelle® Y Polypropylene Mesh as safe and effective treatments of Stress Urinary Incontinence.

229. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and for which Plaintiffs will seek at the appropriate time under governing law, the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with the applicable federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants knowing that it was false or with reckless disregard as to its truth and as a perspective assertion, with the intent that the representation would be acted on by Plaintiffs.

230. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

COUNT XIV: DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

231. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

232. Plaintiffs assert all applicable state statutory and common law rights and theories related to tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

233. Plaintiffs plead that discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff Julie Cruz had been injured, the cause of injury, and the tortious nature of the wrongdoing that caused the injury.

234. Under appropriate applications of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

235. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physician of the true risks associated with the Gynecare TVT™ Obturator System and the Restorelle® Y Polypropylene Mesh. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physician were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and request compensatory damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

i. Compensatory damages in excess of the minimum jurisdictional amount, including, but not limited to, compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined by the trier of fact in this action:

ii. Economic damages in the form of medical expenses, out-of-pocket expenses, life care expenses, and other economic damages in an amount to be determined by the trier of fact in this action;

iii. Attorneys' fees, expenses, and other costs of this action;

iv. Punitive damages; and

v. Such relief as this Honorable Court deems necessary, just and proper.

PLAINTIFFS DEMAND A TRIAL BY JURY

DATED: January 9, 2019

HANSEN, KOHLS, SOMMER & JACOB, LLP

By: */s/ Daniel V. Kohls*
Attorneys for Plaintiffs
JULIE CRUZ and RAY CRUZ

CERTIFIFCATE OF SERVICE

The undersigned counsel for Plaintiffs hereby certifies that a true and correct copy of the foregoing document was filed with the Court and served electronically through the CM-ECF (electronic case filing) system to all counsel of records to those registered to receive Notice of Electronic Filing for this case on January 9, 2019.

Dated: January 9, 2019

HANSEN, KOHLS, SOMMER & JACOB, LLP

By: */s/ Daniel V. Kohls*
Daniel V. Kohls
Attorneys for Plaintiffs
JULIE CRUZ and RAY CRUZ